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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/777,572 | 02/11/2004 | David Burton | 24,577-45CIP | 6003 |

7590 11/13/2006

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| EXAMINER | |
|---|---|
| ALI, SHUMAYA B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3771 | |

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/777,572 | BURTON, DAVID | |
| | Examiner | Art Unit | |
| | Shumaya B. Ali | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *9/4/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

Claims 1-31 are pending in the current application.

### *Response to Arguments*

Applicant's arguments filed on 9/4/2006 have been fully considered but they are not persuasive. In response to Applicant's arguments that Miles fails to specifically teach connection of the sensors to a headgear, it should be noted that Miles does disclose that sensors may be mounted inside the mask or connected to the mask. Since connected to the mask is such a broad disclosure and leaves open the possibility of connection to the mask via various means including but not limited to a headgear. Thus, Applicant's arguments with respect claims 4-6 regarding location of sensor are respectfully found not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Miles discloses a plurality and variety of sensors including an EEG sensor, therefore, it should also be noted that Miles

broadly teaches physiological specific sensor which is located on the respective/correspond anatomy as shown in Figure 2 and therefore, it would have been obvious to one or ordinary skill in the art to place an EEG, which inherently measure/detect brain activity near or on the head and away from mask, i.e. forehead support, in order to get a more precise reading (see col.4. lines 33-35, lines 44-45; lines 55-59; col.5 lines 615, and col.7 lines 37-51).

In response to Applicant's argument that Miles does not teach a processor for determining the state of arousal or adjusting a gas delivery setting based on such a determination, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to Applicant's arguments that Miles does not teach the structure of a processor for determining subject sleep state, and there exists no structure in Miles capable of performing the steps of determining subject sleep state, Applicant are to respectfully recognize that claimed method and apparatus are considered coextensive with one another. Since Miles teaches the apparatus as claimed, the method steps are considered obvious results of using the apparatus.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims1, 4-26,28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US Patent No. 5,353,788**

**As to claims 1,26, Miles disclose** a mask assembly (3,26) comprising: a body (see fig.2, attachment below) having an internal surface (see fig.2, mask inherently have external and internal surface), an external surface (see fig.2, attachment below), and a perimeter surface (see fig.2 attachment below); and a forehead support (see fig.2 attachment below) connected to the body, however does not disclose the forehead support having an EEG sensor located thereon, however, Miles teaches that sensors may be mounted inside the mask or connected to the mask. Since connected to

the mask is such a broad disclosure and leaves open the possibility of connection to the mask via various means including but not limited to a headgear. Miles also discloses a plurality and variety of sensors including an EEG sensor, therefore, it should also be noted that Miles broadly teaches physiological specific sensor, thereby reciting limitation cited in **claims 4,5-7, 28,29** which is located on the respective/correspond anatomy as shown in Figure 2 and therefore, it would have been obvious to one or ordinary skill in the art to place an EEG, which inherently measure/detect brain activity near or on the head and away from mask, i.e. forehead support, in order to get a more precise reading (see col.4. lines 33-35, lines 44-45; lines 55-59; col.5 lines 615, and col.7 lines 37-51).

**As to claims 8-16, 23,30,31 Miles discloses limitation as cited for claim 1** and a processor in communication with the gas delivery device and the sensor, the processor adapted to determine the existence of a sleep disorder and to adjust the gas delivery setting based thereon (see fig.2).

**As to claims 17-22,25, Miles discloses limitation as cited for claims 1,8-16,23,30.** Therefore the structures sited in those claims can be used to perform method steps cited in claims 17-22, and 25.

**Claims 2,3,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US Patent No. 5,353,788 in view of Kwok US Patent No. 6532961 B1**

**As to claims 2,3, and 27 Miles** does not disclose respectively padding and forehead support bar, however mask with such features are well known in the art. Kwok teaches padding (25) and forehead support bar (12). Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to include padding and bar to the mask of Miles in view of Kwok for the purposes of providing cushioning to the forehead using padding and enhance strap attachment with comfort around the forehead (see Kwok col.4 lines 15-20, and 40-45).

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

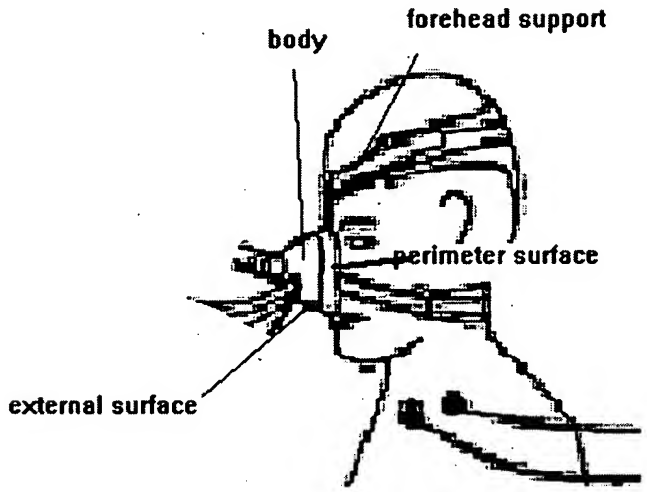
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shumaya Ali 11/11/2006
Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
11/12/06




Prior Art
**U.S. Patent 5,353,788**

Figure 2

11/11/2006